AUG 2 4 2000

K001560

Premarket Notification 510 (k) Summary for the Odontosurge 3

APPENDIX F

Submitter:
Odonto~*Wave*
1136 East Stuart #4203
Fort Collins, CO 80525

Date Summary was prepared: May 15, 2000

Name of the device:

Odontosurge 3

Identification of Predicate device:

ArthroCare Dental Electrosurgery System
ArthroCare Corporation
K962445

Description of the device:

The Odontosurge 3 is a high frequency electrosurgery unit that is comprised of the following three principal components: Control Box, Handpiece and Cord, and Six different Electrodes contained in a separate case. The Odontosurge 3 is compact and easily portable. The Odontosurge 3 is a reusable electrosurgical unit that is used to cut and to coagulate soft tissue during procedures in all disciplines of dentistry. There is no software utilized in the operation of the Odontosurge 3.

Intended use:

The Odontosurge 3 is intended for use in cutting (removing) soft tissue and controlling bleeding in the oral cavity during surgical procedures in all phases of dentistry, including prosthodontics, periodontics, endodontics, pedodontics, orthodontics, oral surgery, and routine restorative dentistry.

Comparison of device characteristics to predicate:

The intended use, sterilization method, and mode of operation of the Odontosurge 3 are the same as the ArthroCare Dental Electrosurgery System. The difference between the two devices is the frequency of operation. However, Odonto~*Wave* believes that this operating frequency offers many convenience and safety advantages.

Conclusion:

The intended use, general design, materials of fabrication, and performance of the Odontosurge 3 are the same as the predicate device, ArthroCare Dental Electrosurgery System and devices already on the market. Therefore, the Odontosurge 3 that is the subject of this 510 (k) is substantially equivalent to dental Electrosurgical units in interstate commerce prior to May 28, 1976.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 2000

Mr. James Dieroff
Marketing and Sales
Odonto-Wave
1136 East Stuart #4203
Fort Collins, Colorado 80525

Re: K001560
Trade Name: Odontosurge 3
Regulatory Class: II
Product Code: EKZ
Dated: August 10, 2000
Received: August 14, 2000

Dear Mr. Dieroff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001560

APPENDIX G

510 (k) Number:

None assigned as of this time

Device Name:

Odontosurge 3

Indications for Use:

The Odontosurge 3 is intended for use in removing soft tissue and controlling bleeding in the oral cavity in all phases of dentistry, including prosthodontics, periodontics, endodontics, pedodontics, orthodontics, oral surgery, and routine restorative dentistry.

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Use (per 21 CFR 801.109)

___ Over–the–counter (OTC) Use

for NSR

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001560